

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

MANNATECH, INC.

Plaintiff,

VS.

GLYCOBIOTICS INTERNATIONAL,
INC.

Defendant.

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NO. 3-06-CV-0471-BD

MEMORANDUM OPINION AND ORDER

In this patent case, plaintiff moves for partial summary judgment on its infringement claims and defendant moves for partial summary judgment on its affirmative defense of invalidity for indefiniteness. For the reasons stated herein, both motions are denied.

I.

Plaintiff Mannatech, Inc. is the owner by assignment of two patents for glyconutritional dietary supplements, U.S. Patent Nos. 6,929,807 ("the '807 Patent") and 7,157,431 ("the '431 Patent"). The '807 Patent claims a dietary supplement composition of nutritionally effective amounts of isolated and purified saccharides for the promotion and maintenance of good health. *See* Plf. MSJ App. at 1-16. The '431 Patent is a continuation of the '807 Patent and shares a common specification. *Id.* at 17-32. In this lawsuit, plaintiff alleges that a dietary supplement manufactured and sold by Defendant Glycobiotics International, Inc. under the brand name Glycomannan™ infringes one or more claims of the '807 and '431 Patents. *See* Plf. First Am. Compl. at 4, ¶¶ 20-24 & 6-7, ¶¶ 38-42. Defendant denies any infringement and maintains that the patents in-suit are invalid for a variety of reasons. *See* Def. Ans. at 3-4, ¶¶ 20-24, 5, ¶¶ 38-42, & 10-11, ¶¶ 1-10.

Plaintiff now seeks summary judgment on its infringement claims and defendant seeks summary judgment on its affirmative defense of invalidity for indefiniteness. The motions have been fully briefed by the parties and are ripe for determination.¹

II.

Summary judgment is proper when there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986). The substantive law determines which facts are material. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 2509-10, 91 L.Ed.2d 202 (1986). In a patent case, a plaintiff who seeks summary judgment on a claim of infringement and a defendant who seeks summary judgment on the affirmative defense of invalidity must establish "beyond peradventure all of the essential elements of the claim or defense." *Aspex Eyewear, Inc. v. E'Lite Optik, Inc.*, No. 3-98-CV-2996-D, 2002 WL 1751381 at *8, 26 (N.D. Tex. Apr. 4, 2002) (citing cases). The burden then shifts to the non-movant to show that summary judgment is not proper. *Duckett v. City of Cedar Park*, 950 F.2d 272, 276 (5th Cir. 1992). The parties may satisfy their respective burdens by tendering depositions, affidavits, and other competent evidence. *Topalian v. Ehrman*, 954 F.2d 1125, 1131 (5th Cir.), *cert. denied*, 113 S.Ct. 82 (1992). All evidence must be viewed in the light most favorable to the party opposing the motion. *Rosado v. Deters*, 5 F.3d 119, 122 (5th Cir. 1993).

A.

Plaintiff contends that the dietary supplement manufactured and sold by defendant under the brand name Glycomannan™ literally infringes claims 1, 5 and 6 of the '807 Patent and claim 8 of

¹ Plaintiff also sues for trademark infringement, business disparagement, tortious interference with existing contracts and prospective business relations, and injury to business reputation. The trademark infringement claim is the subject of a separate motion for summary judgment filed by defendant. Neither party seeks summary judgment on plaintiff's claims for business disparagement, tortious interference, or injury to business reputation.

the '431 Patent. A patent is infringed if every limitation set forth in a claim is present in an accused product either literally or under the doctrine of equivalents. *Seal-Flex, Inc. v. Athletic Track and Court Construction*, 172 F.3d 836, 842 (Fed. Cir. 1999); *Jurgens v. McKasy*, 927 F.2d 1552, 1560 (Fed. Cir.), *cert. denied*, 112 S.Ct. 281 (1991). Where, as here, only literal infringement is alleged, the patentee must prove that the accused product contains each limitation of an asserted claim. *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir.), *cert. denied*, 121 S.Ct. 484 (2000). "If any claim limitation is absent from the accused [product], there is no literal infringement as a matter of law." *Id.*; *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir.), *cert. denied*, 124 S.Ct. 464 (2003); *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812 (Fed. Cir. 2002).

1.

The '807 Patent claims a dietary supplement composition of nutritionally effective amounts of eight isolated and purified saccharides. Claim 1 of the '807 Patent recites:

A dietary supplement composition, comprising: nutritionally effective amounts of isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

Plf. MSJ App. at 15.

Claim 5 of the patent, which is dependent on Claim 1, recites:

A dietary supplement composition according to claim 1, wherein said isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are powdered.

Id.

Claim 6 of the patent, which also is dependent on claim 1, recites:

A dietary supplement composition according to claim 1, wherein said isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are encapsulated.

Id.

The '431 Patent claims a dietary supplement composition of nutritionally effective amounts of isolated and purified acetylated mannose and at least five other saccharides from a list of 13 sugars. Claim 1 of the '431 Patent recites:

A dietary supplement composition comprising: a nutritionally effective amount of isolated and purified acetylated mannose; and a nutritionally effective amount of at least five isolated and purified saccharides selected from: galactose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, iduronic acid and arabinogalactan.

Id. at 31.

Claim 8 of the patent, which is dependent on claim 1, recites:

The dietary supplement composition of claim 1, wherein the acetylated mannose is obtained from the group consisting of aloe vera and acetylated polymannose, and the at least five isolated and purified saccharides are obtained from the group consisting of gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

Id. at 32.

Both the '807 and '431 Patents define "a nutritionally effective amount" as "that amount which will provide a beneficial nutritional effect or response in a mammal." *Id.* at 11, 26. The court previously construed the term "isolated and purified" to mean "separated from other, unwanted

substances." *Mannatech, Inc. v. Glycobiotics International, Inc.*, 513 F.Supp.2d 754, 762 (N.D. Tex. 2007) (Kaplan, J.).

2.

To prevail on its summary judgment motion, plaintiff must prove that Glycomannan™ is (1) a dietary supplement composition (2) comprised of nutritionally effective amounts (3) of isolated and purified saccharides identified in the '807 and '431 Patents. The court has little difficulty concluding that Glycomannan™ is a dietary supplement composition. However, the summary judgment evidence does not establish "beyond peradventure" that the accused product contains "nutritionally effective amounts" of any saccharide claimed by the patents in-suit.

In an attempt to prove that Glycomannan™ contains "nutritionally effective amounts" of the component sugars, plaintiff offers the declaration of Bill McAnalley, a pharmacology-toxicology expert and one of the named inventors of the '807 and '431 Patents. According to McAnalley:

[I]t is my opinion that Glycomannan™ contains nutritionally effective amounts of the isolated and purified saccharides found in Claim 1 of the '807 and '431 Patents. While working for Mannatech, I was primarily responsible for the development of Ambrotose®, another glyconutritional dietary supplement which has been shown to provide a beneficially nutritional effect in persons who have taken it. Based on my comparisons of the formulations of Ambrotose® and Glycomannan™ [], and my review of the dosing instructions for Glycomannan™ [], it is my opinion that Glycomannan™ contains nutritionally effective amounts of the isolated and purified saccharides found in Claim 1 of the '807 and '431 Patents. This opinion is also supported by the testimonials by customers who have used Glycomannan™ who claim to have experienced beneficial effects from taking Glycomannan™.

Plf. MSJ App. at 19-20. McAnalley offered substantially the same testimony at his deposition, explaining that he determined Glycomannan™ infringes the patents in-suit by "looking at the label" and comparing the product to Ambrotose®. *See* Def. MSJ Resp. App. at 5-6. The court cannot

accept this testimony as evidence that Glycomannan™ contains "nutritionally effective amounts" of the various saccharides identified in the '807 and '431 Patents. The Federal Circuit has held that "[i]nfringement is determined on the basis of the claims, not on the basis of a comparison with the patentee's commercial embodiment of the claimed invention." *International Visual Corp. v. Crown Metal Manufacturing Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993), quoting *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1578 (Fed. Cir. 1984). By comparing Glycomannan™ to Ambrotose®, McAnalley bases his infringement determination on a comparison of the two products rather than evidence that the accused product contains each limitation of the asserted claim. This is improper. See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1347 (Fed. Cir. 2003) (accused device must be compared to the patent claims rather than to a preferred or commercial embodiment); *Spectrum International, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1381 (Fed. Cir. 1998) (same); *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir.), cert. denied, 115 S.Ct. 500 (1994) (district court improperly based infringement analysis on a comparison of accused chemical compound to a sample of material of patented chemical compound). Nor can McAnalley rely on the testimonials of Glycomannan™ customers to support his infringement analysis. This type of evidence is wholly unreliable and fails to establish "beyond peradventure" that the accused product contains "nutritionally effective amounts" of the saccharides claimed by the patents in-suit. See *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1355 (Fed. Cir. 2007) (excluding testimony of expert who based infringement analysis on her own interpretation of representations made by accused infringers about their product rather than on any scientific review or analysis of the product itself).²

² Defendant has filed a separate motion to exclude the testimony of various experts who offer opinion evidence in support of plaintiff's motion for summary judgment. See Doc. #149. As grounds for excluding the testimony of Bill McAnalley, defendant points to the absence of any scientific analysis of the Glycomannan™ product and accuses the

The only other evidence offered by plaintiff to prove that Glycomannan™ contains "nutritionally effective amounts" of the saccharides claimed by the '807 and '431 Patents are representations found on the Glycobiotics website, <http://www.glycobiotics.com>. Illustrative of these representations are the following testimonials of Glycomannan™ customers:

I've been using your product for a couple of months now – both myself and my daughter. We're experiencing really good results. I had a pretty severe detox reaction withing [sic] days . . . – which is a good thing. I've been giving my daughter a lot and she's going from strength to strength, this time last year she was lethargic and lacked motivation. Now her energy levels are so much higher.

Stacy's doctor does not need to see him again for 6 months he is doing so well! . . . I have so much more energy, too!

I've just had some major oral surgery and the healing is progressing VERY rapidly plus my fasting blood sugars are down about 25 points[.]

I have used it for two days and already seem to be experiencing a difference. I have much more energy. This is amazing stuff!

I was taking the multi-level supplements, but I kept having relapses and setbacks. So far your Glycomannan™ glyconutrient is doing one heck of a job for me – no relapses, just a very healthful time.

I found a difference in three days. I am a vegetarian, so that probably had an advantage for working so fast. My balancing is better and so is my energy level.

I have much more energy and it seems to agree with my restricted life style. My labs came back with the best report that I've had in a year of dialyzing.

expert of basing his opinion entirely on a review of marketing materials. While defendant oversimplifies and improperly characterizes the contents of McAnalley's declaration, the fact remains that his testimony falls short of establishing that Glycomannan™ contains "nutritionally effective amounts" of the saccharides claimed by the patents in-suit. Because the court has not relied on the testimony of Mark Tengler and Keith Clark, the other experts challenged by defendants, the motion to exclude their testimony is denied as moot. *See Consortium Information Services, Inc. v. National Information Services, Inc.*, No. 3-99-CV-2509-BD, 2001 WL 1516758 at *3 n.5 (N.D. Tex. Nov. 27, 2001) (Kaplan, J.) (overruling as moot objections to affidavits where none of the evidence was necessary to the disposition of pending motion).

One scoop and what a difference! I always get upset about everything, but something changed. A state of total calm – I have never known this type of tranquility before. Also able to do more[.]

I'm not exactly sure what's happening but good things for my husband! 3 changes all at about the same time, adjustment in a medical procedure, Glycomannan™, and a new drug the doctor has him on. Now the next day after he took the Glycomannan™ there were such dramatic changes, I thought he was healed! But the main thing is he is singing again, whistling again, and even working all day long, which he has not had the energy to do for several years. He told me to tell you he feels "a whole lot better, his balance is getting straightened out, and he has more energy[.]"

I always thought I was too young to have as many problems as I did. At 28 years old, I would wake up stiff, achy, with all my joints hurting, and my hands and fingers would always fall asleep during the night. I had acne that nothing seemed to help, and I had extreme sensitivity to sugar and wheat. Eating these made me feel drugged, like I needed a nap. . . . My whole outlook on life now is more positive. I am a better mom, and a better wife. I started walking 2 miles a day, and I can now run around with my kids without my joints hurting. My skin is improving, and because I've felt so good, I've naturally been more energetic and haven't had the food cravings that I had struggled with every single day. This change has helped me lose 10 pounds! It's like I feel myself healing on the inside. I forget how it feels to be depressed and hurting all the time.

Plf. MSJ App. at 260-61. Even if these unsworn statements from unidentified sources constitute admissions attributable to defendant,³ they do not establish "beyond peradventure" that the accused

³ Under the Federal Rules of Evidence, an out-of-court statement may be offered against a party-opponent if the statement is:

(A) the party's own statement, in either an individual or a representative capacity, or (B) a statement of which the party has manifested an adoption or belief in its truth, or (C) a statement by a person authorized by the party to make a statement concerning the subject, or (D) a statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship, or (E) a statement by a coconspirator of a party during the course and in furtherance of the conspiracy.

FED. R. EVID. 801(d)(2). If plaintiff can establish one of these exceptions to the hearsay rule, the customer testimonials appearing on the Glycobiotics website may be admissible at trial. *See PharmaStem*, 491 F.3d at 1351 ("[T]here is no prohibition against using the admissions of a party, whether in the form of marketing materials or otherwise, as evidence in an infringement action[.]").

product contains "nutritionally effective amounts" of any sugar. Significantly, none of these statements address the claim limitation that the product contain any particular ingredient. Rather, the testimonials are unsubstantiated assertions by customers who experienced some perceived health benefit after taking Glycomannan™. Moreover, the probative value of these customer testimonials is weakened by the accompanying disclaimer on the Glycobiotics website:

The statements made at this website have not been evaluated by the Food and Drug Administration. The products are not intended to diagnose, treat, cure or prevent any disease. Any scientific information that we may give you or lead you to is for your education and is not to be used as a substitute for a health provider's care or proven therapy.

Id. at 262. Without deciding whether these testimonials are admissible at trial as admissions by defendant, they are wholly insufficient at the summary judgment stage to prove that Glycomannan™ contains "nutritionally effective amounts" of the sugars claimed by the patents in-suit. This failure of proof precludes summary judgment in favor of plaintiff on its infringement claims.

B.

Defendant argues that both the '807 and '431 Patents are invalid for indefiniteness. Under section 112 of the Patent Act:

[A patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993), *cert. denied*, 114 S.Ct. 943 (1994); *see also North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993), *cert. denied*,

114 S.Ct. 1645 (1994). However, a patent that fails to meet this requirement is invalid for indefiniteness. *See Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Indefiniteness is a question of law and must be proved by clear and convincing evidence. *See Touchcom, Inc. v. Dresser, Inc.*, 427 F.Supp.2d 730, 732-33 (E.D. Tex. 2005) (citing cases).

The '807 and '431 Patents require the component saccharides to be "isolated and purified," a term the court has construed to mean "separated from other, unwanted substances." *Mannatech*, 513 F.Supp.2d at 762. In light of this construction, defendant argues that the claim term is vague and indefinite because neither the patents themselves nor the intrinsic record provide an objective standard to determine the *precise* degree of "isolation" or "purification" or specify *exactly* what "unwanted substances" must be removed in order to practice the invention. *See* Def. MSJ Br. at 3-4. The court disagrees. Exact precision is not required to avoid invalidity on grounds of indefiniteness. Rather, the claim language need only be as accurate as the subject matter permits. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986); *see also Power-One, Inc. v. Artesyn Technologies, Inc.*, No. 2-05-CV-0463, 2007 WL 896093 at *5 (E.D. Tex. Mar. 22, 2007) (citing cases). Here, the intrinsic record demonstrates that the claimed invention is comprised of at least six different saccharides each available from a number of natural and synthetic sources. Other evidence shows that the degree of isolation and purification required, as well as the identity of any unwanted substances, differs depending on the source. *Compare* Plf. MSJ Resp. App. at 36-37 (describing simple cleansing and sorting required to separate gum ghatti and gum tragacanth from dirt and bark) *with id.* at 61 (describing multiple steps required to separate aloe vera gel from anthraquinones, a laxative, and fibrous plant material). The court therefore determines that the "isolated and purified" limitation is reasonably precise in light of the subject matter.

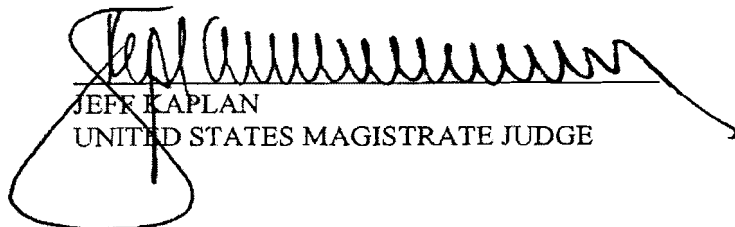
Nor is the court's construction of this claim term fatally indefinite. To the contrary, the court's construction of "isolated and purified" is consistent with interpretations of the claim term by expert witnesses skilled in the art of dietary supplements and related sciences. *See Mannatech*, 513 F.Supp.2d at 762. No expert has suggested that the term "isolated and purified" is so vague that it cannot be given any meaning at all.⁴ Thus, the term is not "insolubly ambiguous" so as to be indefinite. *See Amgen*, 314 F.3d at 1342. Defendant is not entitled to summary judgment on its affirmative defense of invalidity for indefiniteness.

CONCLUSION

Plaintiff's motion for partial summary judgment on its infringement claims [Doc. #129] and defendant's motion for partial summary judgment on its affirmative defense of invalidity for indefiniteness [Doc. #132] are denied. The court will set this case for trial by separate order.

SO ORDERED.

DATED: December 14, 2007.



JEFF KAPLAN
UNITED STATES MAGISTRATE JUDGE

⁴ In its claim construction brief, defendant proposed that "isolated and purified" meant "obtained alone with other components removed therefrom, i.e. with a purity level of at least 95%." *See Mannatech*, 513 F.Supp.2d at 758. Although this definition was not adopted by the court, the fact that defendant proffered a proposed construction of this claim term undermines its argument that the term is "insolubly ambiguous" and not amenable to construction. *See Wireless Agents, L.L.C. v. Sony Ericsson Mobile Communications AB*, No. 3-05-CV-0289-D, 2007 WL 273568 at *3 (N.D. Tex. Jan. 31, 2007) (claim term not indefinite where party asserting invalidity had proffered a construction for the term); *Power-One*, 2007 WL 896093 at *5 n.3 (same).